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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,947	07/25/2003	Lawrence Edward Dolan	9117M	3220

27752 7590 02/06/2006

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EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 02/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/626,947	Applicant(s) DOLAN ET AL.	
	Examiner Frederick F. Krass	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

New Matter Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "new matter" rejection.

Applicant states that support for the newly added limitations regarding relative colorant particle levels can be found in the examples and on page 6, lines 17-21. (Remarks, p. 4, ¶ 1). The examiner acknowledges that support for the specific ranges recited in claim 11 is found at p. 6, lines 17-21 (which subsume the specific amounts used in the working examples), but does not agree that adequate support is found for the broader recitation "wherein the level of colorant particles in the first phase(s) is greater than the level of colorant particles in the second phase(s)" in amended claim 1. The courts have recognized that a narrower, closed range (that recited in claim 11) does not provide adequate support for an open-ended range (that recited in claim 1): see In re Wertheim, 541 F.2d 257, 191 U.S.P.Q. 90 (CCPA 1976). (Holding that a new,

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open-ended claim limitation of “at least 35%” was not supported by an originally described, closed range of 25-60% (specific values of 36 and 50% having been used in the original working examples) because the new, open-ended limitation caused the claims to read on literal embodiments outside the originally described, closed range).

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “about” permits some tolerance and is generally definite. See, for example, In re Ayers, 69 USPQ 109 (CCPA 1946), where “at least about 10%” was held to be anticipated by a teaching of a content “not to exceed about 8%.” Where close prior art exists, however, the term “about” can become indefinite, with Applicant bearing the burden of establishing that the term is sufficiently clear to avoid such art. See specifically Amgen v. Chugai, 927 F.2d 1200 (Fed. Cir. 1991), where the court found the recitation of a specific activity of “about” 160,000 indefinite since it gave no hint as to which value between the prior art value of 128,620 and 160,000 constituted infringement. As noted at page 1218 of the decision, the holding was further supported by the fact that “nothing in the specification, prosecution history, or prior art provides

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any indication as to what range of specific activity is covered by the term". That is the case here: nothing in the instant specification, prosecution history, or prior art provides any indication as to what values would be covered by the claimed term "about".

In the instant case, close prior art (USP 6,315,986) exists which renders the term "about" indefinite, per the reasoning of the Amgen decision. See the discussion accompanying the "Obviousness" section infra.

Obviousness Rejection

Claims 1-9 were rejected under 35 USC 103(a) as being unpatentable over Stier (EP 076,563) in view of Wong et al (USP 6,315,986).

This rejection is maintained and is now applicable to claims 1-11.

Applicant argues that no prima facie case exists since neither the primary nor secondary reference discloses phases having different levels of colorants. (Remarks, p. 4, ¶¶ 3-5).

The examiner disagrees.

Firstly, the factual accuracy of Applicant's statement appears in doubt. There will always be a slight, albeit miniscule, statistical difference in colorant level in each phase. That inherent statistical variation falls within the scope of instant claims 1-10 because they a) do not require any specific relative proportions, only that the levels be "different" and b) they provide no clear line of demarcation between the "first" and "second" phases, other than to specify that they have contrasting colors. Moreover, the examiner

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notes that Example II of the secondary reference discloses a two phase composition in which the first phase initially contains 0.5 percent blue colorant particles, and the second phase initially contains 1.0 percent opacifier (titanium dioxide), but not colorant. After storage, however, 5 to 8 percent bleeding occurs (col. 7, lines 25-35), *i.e.*, the second phase then contains a smaller amount of colorant than the first phase.

The same reasoning is believed to apply to claim 11, insofar as the term “about” is rendered indefinite by the presence of close prior art, per the reasoning provided in the “Indefiniteness” section supra. Specifically, claim 11 is inclusive of a composition in which the first phase contains “about” 0.6 percent colorant particles, and the second phase contains “about” 0.5 percent. The instant specification provides no guidance as to how far “about” extends these values, so the claim is read upon by a prior art composition containing 0.5 parts colorant in each phase (such as those disclosed in working example 1 of the secondary reference) since some statistical variation will always exist, whether due to slight errors in reagent measurement, redistribution due to diffusion equilibrium between the two phases, etc.¹

Secondly, even assuming (purely *arguendo*) that mere statistical variation in colorant levels would not be within the scope of the instant claims, a fair case of prima facie obviousness would in fact exist. The courts have long recognized that, normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. See, e.g., In re Aller 105

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USPQ 233, 235 (CCPA 1955); see also In re Peterson, 315 F.3d 1325 (C.A. Fed. 2003)(reaffirming the reasoning of the Aller decision). The relative amounts of colorant required will vary in a colorant-dependent fashion according to basic principles of color-indexing, and thus are “result effective variables”.² It would have been obvious to have varied those amounts to optimize the contrast in color sought by the prior art, per the reasoning of the Aller decision.

Applicant further states that one advantage of the present invention is lower manufacturing cost resulting from the use of one type of colorant to develop a contrasting striped dentifrice using a lower level of colorant particle in the paste phase (opacified phase) and a higher level of colorant particle in the transparent phase. Since fewer ingredients are needed, Applicant reasons, lower costs and simplified processing and manufacturing are achieved. (See the passage bridging pages 4 and 5 of Applicant’s response).

The examiner does not find these arguments persuasive. Firstly, the claims do not require that the colorant particles in each phase be the same, so even if unexpected results are shown, the claims would not be commensurate in scope with that showing. (The instant claims would in fact appear to require different colorants, since claim 1 specifically recites that the “first phase and the second phase have contrasting colors” (emphasis added). Furthermore, it is not clear that any unexpected results have actually been shown; no factual evidence is seen to support these allegations. If the

¹ Note that EP 0 076 563 verifies that the skilled artisan would expect just that phenomenon to naturally occur (p. 2, line 14).

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same colorant is used in each phase, it logically follows that less mixing is required, and that only one pigment need be purchased. In other words, lower costs and simplified processing would be expected, and thus would not constitute probative secondary evidence of patentability.

Action is Final

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

² In other words, when a strong color was contrasted with a weak color, the former would require correspondingly less colorant, and the latter corresponding more, to provide equal levels of intensity.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614

